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"If we did anything which suggested we were simply in the nicotine delivery business, we would run a serious risk of facing FDA jurisdiction."[1222] There was no suggestion in any of the submitted documents that any claims would be placed on cigarettes as a result of the company's sale of nicotine patches. Nevertheless, the company recognized that FDA jurisdiction might follow solely based on evidence suggesting company knowledge that cigarettes are related to other nicotine delivery systems. The company ultimately chose not to become involved in the sale of nicotine patches. For these reasons, *Flood v. Kuhn* is inapplicable.

[1222] McGraw M, *Nicotine Delivery Systems* (Apr. 24, 1992), at 1. *See* AR (Vol. 531 Ref. 124).

VI. FDA EMPLOYED PROCEDURES THAT PROVIDED AN OPPORTUNITY FOR FULL PUBLIC PARTICIPATION AND EXCEEDED ALL LEGAL REQUIREMENTS

The Agency went to great lengths to involve the public in the process by which the Agency made its final jurisdictional determination. On February 25, 1994, FDA Commissioner David Kessler wrote to Scott Ballin, chairman of the Coalition on Smoking OR Health, regarding the possibility of FDA regulation of cigarettes in response to certain petitions that had been filed with the Agency. The Commissioner explained:

> [T]he agency has examined the current data and information on the effects of nicotine in cigarettes. . . . Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. . . . This evidence . . . suggests that cigarette vendors intend the obvious -- that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products . . . .[1223]

The letter was made publicly available and covered by the press.[1224]

[1223] Letter from Kessler DA (FDA) to Ballin SD (Coalition on Smoking OR Health) (Feb. 25, 1994). *See* AR (Vol. 35 Ref. 365).

[1224] Neergaard L (Associated Press) FDA considers calling nicotine a drug, banning cigarettes (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 30).

Associated Press, FDA considers classification of nicotine as drug, *Chicago Tribune* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 31).

Chen E, Government agency claims power to ban nearly all cigarettes; FDA fears nicotine used for addiction, *The Houston Chronicle* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 32).

Chen E, In shift, FDA says it could classify nicotine as a drug, *Los Angeles Times* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 33).

Hilts PJ, U.S. Agency suggests regulating cigarettes as an addictive drug, *New York Times* (Feb. 25, 1994). *See* AR (Vol. 711 Ref. 34).

Tribune News Services, *The Salt Lake Tribune* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 35).

VI.

In the months that followed, Commissioner Kessler testified twice before Congress regarding the accumulating evidence relating to the intended use of cigarettes.[1225] That testimony was extensive and detailed.

In July and August of that year, FDA Associate Commissioner for Regulatory Affairs Ronald G. Chesemore wrote to all of the major cigarette and smokeless tobacco companies requesting all documents relating to "all research on nicotine . . . , including their pharmacological effects, and all documents relevant to nicotine" in their products.[1226] On August 1, 1994, FDA held a Drug Abuse Advisory Committee meeting that was fully open to the public on the subject of the abuse potential of nicotine.

On August 11, 1995, FDA provided the public with an extensive *Federal Register* document analyzing the Agency's authority to assert jurisdiction over cigarettes and smokeless tobacco based on the evidence before the Agency at that time. *See* Jurisdictional Analysis, 60 FR 41453–41787. This document, which accompanied the Agency's announcement of its proposal to regulate the sale and distribution of cigarettes and smokeless tobacco, *see* 60 FR 41314–41375, provided the public with a full view of

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FDA claims authority to regulate nicotine; agency cites manipulation of cigarette 'drug,' *St. Louis Post Dispatch* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 36).

Schwartz J, In policy shift, FDA is ready to consider regulating tobacco, *The Washington Post* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 37).

[1225] Statement by David Kessler, M.D., Commissioner of Food and Drugs, on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994). *See* AR (Vol. 1 Appendix 7).

Statement by David Kessler, M.D., Commissioner of Food and Drugs, on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Jun. 21, 1994). *See* AR (Vol. 1 Appendix 8).

[1226] *See*, e.g., Letter from Chesemore RG (FDA) to Bible GC (Philip Morris Inc.) (Jul. 11, 1994) See AR (Vol. 1 Appendix 3)

the Agency's legal analysis. In addition, the Jurisdictional Analysis was supported by over 600 footnotes, each of which identified for the public the evidence on which the Agency relied to support its findings. The Agency also placed on the record 313 pages of appendices related to the Jurisdictional Analysis.

On August 16, 1995, the Agency put on public display some 20,000 pages of materials that it cited in the Jurisdictional Analysis and the proposed rule. With the exception of three documents, discussed below, the Agency made available to the public all of the materials on which it relied to support the Jurisdictional Analysis and the Proposed Rule. On September 29, 1995, the Agency supplemented the administrative record by putting on public display approximately 13,000 documents comprising some 190,000 pages of factual and analytical materials the Agency considered in the course of issuing the Jurisdictional Analysis and the Proposed Rule. Although it was under no legal obligation to do so, the Agency made these additional materials available because of the importance of the jurisdictional issue and the Proposed Rule.

The administrative record also includes the comments received from the public, as discussed in more detail below. The Agency received over 700,000 comments, some directed to the Jurisdictional Analysis, some directed to the Proposed Rule, and many with overlapping discussions. Though many comments consisted of form letters, the Agency received over 95,000 distinct or unique sets of comments. The cigarette manufacturers jointly submitted 2,000 pages of comments and 45,000 pages of exhibits. The smokeless tobacco manufacturers jointly submitted 474 pages of comments and 3,372 pages of exhibits. The initial comment period remained open for 144 days.

VI.

The Agency also made one other significant addition to the public record relating to its jurisdictional determination. On March 20, 1996, the Agency published a notice in the *Federal Register* providing an additional 30 day comment period limited to specific documents the Agency added to the docket in support of its Jurisdictional Analysis. *See* 61 FR 11419. These materials consisted of declarations and a report from three former tobacco industry employees.

In addition, as discussed further below, the Agency has added to the final record of the jurisdictional determination a comparatively small number of documents that expand upon or confirm information made available in the Jurisdictional Analysis or the Proposed Rule, or that address alleged deficiencies in the Agency's initial record.

Despite the Agency's efforts to involve the public in this jurisdictional determination, FDA received several comments regarding the procedures the Agency followed in publishing the Jurisdictional Analysis. Some of these comments complained that the Agency designated certain documents in the administrative record supporting the Jurisdictional Analysis as "confidential," and that the shielding of these documents denied the public a meaningful opportunity to comment on the Agency's analysis. One of these comments also contended that FDA refused to disclose nonconfidential information on which the Agency relied in the Jurisdictional Analysis. Some comments claimed that FDA failed to set forth a balanced view of the issues raised in the Jurisdictional Analysis. Instead, they argued, FDA concealed certain issues in order to deny the public the opportunity to comment on the Agency's analysis. At least one interested person also maintained that the comment period was so short as to be arbitrary and capricious.

Finally, one comment objected to the Agency's use of certain affidavits and reports from former tobacco industry scientists without first providing the public an opportunity to cross-examine these individuals. However, other than this one comment on a narrow category of evidence in the administrative record, the Agency received no comments concerning, and no objection to, the Agency's decision to use a notice-and-comment type format to reach a final jurisdictional determination.[1227]

As the discussion that follows demonstrates, the procedures the Agency employed in reaching its final jurisdictional determination exceeded the requirements of the APA, the case law construing the APA, and the Agency's own procedural requirements either for a jurisdictional determination or for a conventional informal rulemaking.

A. ADEQUACY OF THE RECORD

Several tobacco industry comments complained about the adequacy of the record in support of the Jurisdictional Analysis. They contended that the Agency violated the APA, 5 U.S.C. 553(b) and (c), and the Due Process Clause of the Fifth Amendment to the Constitution, [1228] by failing to disclose all of the information the Agency "considered or

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[1227] Because of the unique importance of the jurisdictional issue, the Agency published the Jurisdictional Analysis in the *Federal Register* and invited comments on it. The Agency, however, was not required by the Administrative Procedure Act (APA) to invite public comment on the issue of the Agency's jurisdiction. Likewise, the Act neither requires that the Agency commence a rulemaking proceeding, nor conduct a formal evidentiary hearing, before it makes a jurisdictional determination. Nevertheless, because of the great importance of this issue, FDA employed a notice-and- comment-type procedure to give the public an opportunity to participate in the Agency's analysis of its jurisdiction. None of the comments the Agency received identified a statutory requirement that would have compelled the Agency to follow any additional or different procedures. Thus, while the Agency endeavored in its publication of the Jurisdictional Analysis to provide notice, a supportive record, and a comment period sufficient to meet the procedural requirements of the APA for informal rulemaking, the Agency was not bound by the APA's informal rulemaking procedures with respect to the Jurisdictional Analysis.

[1228] Because the APA in this context provides the public at least as much protection as the Due Process Clause of the Constitution, the Agency will address these procedural objections solely under the APA. *See Forester v. Consumer Product Safety Commission*, 559 F.2d 774, 787 (D.C. Cir. 1977); *Ass'n of National Advertisers, Inc., v. Federal Trade Commission*, 627 F.2d 1151, 1166 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1981).

relied upon in the proceeding."[1229] In particular, these comments complained that the public was deprived of the opportunity to comment meaningfully on the Jurisdictional Analysis because, according to these comments, the Agency had relied on confidential documents and on substantial amounts of undisclosed data. One comment went so far as to claim that "a substantial portion" of the material FDA relied upon, both in the Jurisdictional Analysis and in the Proposed Rule, was not made available for public scrutiny.

The record in support of the Jurisdictional Analysis provided the public not only with a "reasonable opportunity" for comment, but with an extraordinary opportunity to examine the Agency's position. The claim that the Agency withheld "a substantial portion" of the materials on which it relied is simply unfounded.

1. The Administrative Record the Agency Assembled for This Proceeding Surpassed the Requirements of the APA

Even in an informal rulemaking proceeding—which the Jurisdictional Analysis was simply modeled on—the APA requires only that the "notice of proposed rule making" include a statement of the time, place, and nature of the proceeding, "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *See* 5 U.S.C. 553(b). The APA, thus, does not expressly require disclosure of the information on which the Agency relies in proposing a rule.

[1229] Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 1. *See* AR (Vol. 535 Ref. 96)

Nevertheless, courts have implied under the APA a requirement that an agency give notice of the information on which it actually relies to support a proposed rule, and make that information available to the extent it is not readily accessible to the public. *See generally* K. Davis, *Administrative Law Treatise*, § 7.3 at 305-309 (3d ed. 1994) (discussing one of the seminal cases on disclosure of data relied on to support a rulemaking proceeding, *Portland Cement Ass'n v. Ruckelshaus,* 486 F.2d 375 (D.C. Cir. 1973), *cert. denied,* 417 U.S. 921 (1974)). No court, however, has required the degree of public disclosure at the notice stage of a rulemaking proceeding that FDA undertook here.

Indeed, the primary cases cited by the comments, namely, *Portland Cement Ass'n, United States v. Nova Scotia Food Products Corp.,* 568 F.2d 240 (2d Cir. 1977), and *United States Lines, Inc. v. Federal Maritime Commission,* 584 F.2d 519 (D.C. Cir. 1978), address agency conduct that bears little resemblance to FDA's efforts in this proceeding. While FDA has provided a remarkable degree of factual support and procedural openness, these cases involve instances in which agencies provided the public with no information whatsoever or otherwise excluded a study that was critical to the agency's decision. In *Portland Cement Ass'n,* the Environmental Protection Agency failed altogether to provide the public an opportunity to comment on the test results and procedures on which the agency relied as the "critical" basis for the emission control level adopted by the agency. That is, the agency set very specific technical control limits, but failed to make public until after the close of the comment period the details of crucial tests relied upon to determine the limits. 486 F.2d at 392.

In *Nova Scotia Food Products,* "all the scientific research was collected by the agency, and *none of it was disclosed* to interested parties as the material upon which the

proposed rule would be fashioned." 568 F.2d at 251 (emphasis added). And in *United States Lines,* where a common carrier challenged an order of the Federal Maritime Commission amending a contract between two competitors, the court found that the Commission had made "critical findings" on the basis of data which was neither identified in its decision nor included in the administrative record. Rather, the Commission based its decision on "reliable data reposing in the Commission's files." 584 F.2d at 533. The reviewing court simply had no idea of the factors or data on which the Commission had relied. *Id.*

Thus, at most, the case law requires agencies to disclose studies and data actually relied upon by the agency. Even then, the cases that have struck down agency rulemaking are generally confined to instances in which the agency provided woefully inadequate information to the public or failed to disclose a critical piece of information. *See, e.g., Kennecott Corp. v. Environmental Protection Agency*, 684 F.2d 1007, 1018-1019 (D.C. Cir. 1982) (agency acted arbitrarily and capriciously when it failed to include in the public docket during the comment period any documents supporting a particular proposed regulation); *compare Personal Watercraft Industry Ass'n v. Department of Commerce*, 48 F.3d 540, 544-545 (D.C. Cir. 1995) (while agency must disclose information critical to its decision to regulate a particular activity, absent prejudice an agency may rely on studies developed after close of comment period that are not critical to the underlying proposal).

Finally, FDA's own procedural regulations require that the Agency include with a notice of proposed rulemaking, among other things, "references to all *information on which the Commissioner relies for the proposal.*" 21 CFR 10.40(b)(vii) (emphasis added); *see* 21 CFR 10.3 (defining the term "administrative record" to mean the materials on

which the Agency "relies to support the action"). Thus, even under the Agency's own procedural regulations, FDA is required—when it initiates informal rulemaking—to supply the public only with the materials the Agency is relying upon to support the proposed action.

Here, the materials the Agency relied upon at the opening of this proceeding are the materials the Agency cited in the two August 11, 1995, *Federal Register* documents. Not only did the Agency provide these materials to the public, but it also provided the roughly 190,000 pages of factual and analytical materials the Agency considered but did not rely on and, hence, did not reference in either the Jurisdictional Analysis or the Proposed Rule. Moreover, the Agency provided over 1000 endnotes and footnotes directing readers to each document, including every study, government report, journal article, industry document, and Agency record on which FDA relied to support the Jurisdictional Analysis and the Proposed Rule.

Out of all of this material, the only nonpublic materials on which the Agency relied in its Jurisdictional Analysis were two confidential documents[1230] and two lines of text the Agency redacted from a document placed on the public Administrative Record.[1231] None

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[1230] The two confidential documents the Agency directly referenced, which are discussed in detail in the text, are the *1991 Handbook on Leaf Blending and Product Development* (Confidential Document 75) and the unredacted summary of notes of FDA trip visits (Confidential Document 74). The summary was compiled from notes and handouts that are also designated as confidential (Confidential Documents 69, 70, 71, 72 and 73). The Agency views the summary as a stand-alone document to the extent it distills a large volume of disparate handwritten notes and handouts. Also, the Agency cited only to the summary itself. Nevertheless, even if the summary were counted as five documents rather than one, the Agency at most relied for support on six confidential documents.

[1231] On page 255 of the Jurisdictional Analysis (60 FR 41716), the Agency redacted several lines of text along with a footnote that identified the sources for the redacted text. The footnote consisted of references to two sources, both of which appeared on the agency's public docket: Kiefer JE, Tennessee Eastman Company, *Cigarette Filters for Altering the Nicotine Content of Smoke* (Report No. 71 5003 7), Aug. 18, 1971 at 1-2, *See* AR (Vol. 28 Ref. 463-1); and Curran Jr. JG, Miller EG, Factors influencing the elution of high boiling components of cigarette smoke from filters, *Beitr. Tabakforsch* 1969;5:67, *See* AR (Vol.